

Applicant : David R. Hennings, et al.
Appl. No. : 10/699,212
Examiner : David M. Shay
Docket No. : 15487.4002

Remarks

Claims 1-17, 19-23 and 25-34 are pending in this application. No amendments have been made, and claims 35-46 have been added. No new subject matter has been added.

Claims 1, 2, 6, 7 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldman et al. ('084) in combination with Dew et al.. (Though not stated, it is presumed that independent claim 14 is included in this rejection as well). Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldman et al. in combination with Dew et al. and Roth et al.. Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldman et al. in combination with Dew et al. and Conn et al.. Claims 9-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldman et al. in combination with Dew et al. and Makower et al. Claims 14-17 and 20-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower et al. in combination with Dew et al. and Roth et al; however, the applicants note that claim 14 does not require a pullback mechanism, which is the basis for the examiner's citation of Makower et al. Thus, as stated above, it is presumed that claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldman et al. ('084) in combination with Dew et al.. Claim 19 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in combination with Dew et al., Roth et al., and Conn et al.. No detailed reasons were set forth for the rejections of claims 26-34, but it is presumed to be for the same reasons as claim 25.

It is respectfully submitted that the claims pending in the present application are patentable over the prior art of record for the reasons discussed below. As a preliminary matter, a telephone interview was had on October 28th between the Examiner David Shay and the Applicants' attorney, Joseph Liu. The Applicants want to express their gratitude to the Examiner for taking the time to speak with Mr. Liu. The Applicants' primary reason for making contact with the Examiner was to discuss the pending 103 rejection.

As a recap, all of the pending claims are directed to the endovenous treatment of varicose veins using a laser having a wavelength between about 1.2 and about 1.8 μm . As explained in the specification, such a laser targets the water and collagen of the vessel wall of the varicose vein and transmits through any residual blood in the treatment area. In contrast, the prior art

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systems for treating varicose veins with lasers generally use wavelengths of 810, 940, and/or 1065 μm , which are primarily absorbed by the blood in the treatment area and not the water and collagen in the vessel wall. New claims 35-46 differ from the claims earlier presented in that water in the vessel wall is recited as a chromophore for laser energy having the recited wavelength (these claims are substantial duplicates of some of the claims in published application no. 2005/0015123 to Paithanker, which is not prior art and was filed on June 30, 2004 based on a provisional application filed on June 30, 2003).

The two references relied upon by the Examiner in maintaining his rejections for claims 1, 2, 6, 7, 14 and 25 are Goldman et al. and Dew et al. Goldman et al. makes a passing reference to treating varicose veins with lasers generally but is silent on the claimed range of wavelengths. (Col 7, l. 57 of Goldman et al.) Dew et al. discloses nothing about treating varicose veins, but does disclose the use of a laser with a wavelength of 1.32 μm for skin closure of a wound. (Col. 11, ll. 27-54 of Dew et al.). The Examiner's 103 rejections for claims 1, 2, 6, 7, 14, and 25 are based upon the combination of these two references. During the interview, the Examiner reiterated that he considered the combination to be proper; however, the Examiner also suggested that he would reconsider his position were the Applicants to submit evidence that the state of the art prior to the invention teaches away from such a combination. *See, e.g., In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003) ("an applicant may rebut a prima facie case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect."). The Applicants gratefully acknowledge the Examiner's suggestion and accordingly submit such evidence, which is summarized below:

Exhibit A: Robert J. Min, MD et al., *Endovenous Laser Treatment of Saphenous Vein Reflux: Long-Term Results*, JOURNAL OF VASCULAR AND INTERVENTIONAL RADIOLOGY, August 2003, at 991. On page 995 of the article, Dr. Min strongly recommends the use of an 810 μm wavelength laser to treat varicose veins. Dr. Min suggests that such a wavelength is preferable over higher wavelengths because 810- μm laser energy is more homogenous due to being absorbed "by blood lining the vein wall"; whereas higher wavelengths, "such as 1,064 nm, which are absorbed less by blood and more by water," are undesirably "less-homogenous." Not only does this article suggest that higher wavelengths are less desirable, the example higher

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wavelength cited, i.e., 1,064 nm, is still lower than the claimed range of wavelengths in the present invention, i.e., about 1,200 nm to about 1,800 nm. Thus, this article teaches away from the use of the claimed range of wavelengths for treating varicose veins, i.e., wavelengths that primarily target water and not blood.

Exhibit B: T.M. Proebstle, MD et al., *Thermal Damage of the Inner Vein Wall During Endovenous Laser Treatment: Key Role of Energy Absorption by Intravascular Blood*, DERMATOLOGIC SURGERY, July 2002, at 596. This article similarly recommends the use of 940 nm, 810 nm, and 980 nm laser energy for the treatment of varicose veins and concludes, on the first page, that "[i]ntravascular blood plays a key role for homogenously distributed thermal damage of the inner vein wall during EVLT [(endovenous laser treatment) for varicose veins]." Moreover, on page 599 of the article, the authors state that "it can be concluded that heat generation by laser absorption cannot play a major role within a saline-filled vein," i.e., a vein not filled with blood. Thus, it is clear that the primary target for the EVLT described in this article is intravascular blood, not water. Accordingly, this article also teaches away from the use of the applicants claimed invention.

Exhibit C: T.M. Proebstle, MD et al., *Endovenous treatment of the greater saphenous vein with a 940-nm diode laser: Thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles*, JOURNAL OF VASCULAR SURGERY, April 2002, at 729. This article is by the same author of Exhibit B and again urges targeting the blood with laser energy in the treatment of varicose veins.

In light of the submitted documents demonstrating that the prior art teaches away the combination of Goldman et al. and Dew et al., the Applicants respectfully submit that pending independent claims 1, 14, 25, and 35 and their respective dependent claims 2-13, 15-24, 26-34, and 36-46 in the present application are directed to patentable subject matter for at least the reasons set forth above and a favorable action is respectfully solicited.

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Conclusion

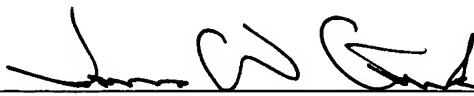
Prompt and favorable action on the merits of the claims is earnestly solicited. Should the Examiner have any questions or comments, the undersigned can be reached at (949) 567-6700.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,

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